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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,989	12/13/2000	Johan H. Geerke	ARC2940R1	5705

7590

02/26/2003

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EXAMINER

DEWITTY, ROBERT M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/735,989

**Applicant(s)**

GEERKE, JOHAN H.

**Examiner**

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13, 15 is/are rejected.
- 7) ☒ Claim(s) 7-9 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-9, and 13-15 are pending in the instant application.

1. Claims 7-9 and 14 are objected to as being dependent on rejected independent claims.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4, 5, 6, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayer (GB 2,174,299).

Ayer teaches an outer wall of semipermeable material defining an interior compartment containing a therapeutic agent (page 2, lines 68-95). Page 3, lines 1-15 teach a laser-formed exit in the outer wall wherein the hydrogel and wax fills the passageway and remains intact during formation. The hydrogel/wax is a region corresponding to the laser exit orifice.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer (GB 2,174,299), further in view of Ayer et al. (U.S. Pat. No. 4,285,987) and Theeuwes et al. (U.S. Pat. No. 4,088,864).

Ayer teaches an outer wall of semipermeable material defining an interior compartment containing a therapeutic agent (page 2, lines 68-95). Page 3, lines 1-15 teach a laser-formed exit in the outer wall wherein the hydrogel and wax fills the passageway and remains intact during formation. The hydrogel/wax is a region corresponding to the laser exit orifice. However, Ayer does not teach that the barrier hydrogel/wax layer surrounds the interior compartment.

Ayer et al. (U.S. Pat. No. 4,285,987) teaches a hydrogel layer surrounding an interior compartment (figure 3 and col. 4, lines 5-26). The hydrogel may be made of polymers that have melting points below 200°C (col. 14, lines 6-47) and are equivalent to the hydrogel/wax layer of Ayer '299.

Theeuwes teaches making passageways using lasers. CO<sub>2</sub> lasers are taught to be more efficient for using as opposed to lasers with higher or lower wavelengths (col. 4, lines 30-34).

It would have been obvious to one having ordinary skill at the time the invention was made to surround an interior compartment with hydrogel to provide both sides of the device with a closing means for the laser drilled passageway.

The teachings of Theeuwes that CO<sub>2</sub> lasers are suitable for use in forming

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passageways, one with ordinary skill in the art would have been motivated to use a layer surrounding the compartment and the use of CO<sub>2</sub> lasers to form passageways.

### ***Response to Arguments***

4. Regarding Applicant's arguments submitted 1/8/03, Applicant asserts that Theeuwes et al. does not teach the limitations of a dosage forms having a barrier layer. The examiner reminds the Applicant that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Ayer clearly teaches an outer wall of semipermeable material defining an interior compartment wherein a hydrogel and wax fills the passageway and remains intact during formation.

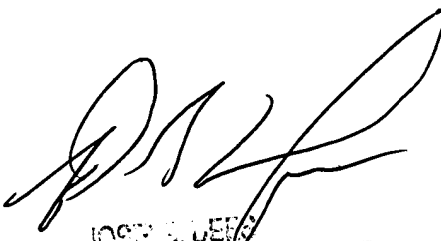
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
February 23, 2003

  
JOSE S. LOPEZ  
SUPERVISORY PATENT EXAMINER

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